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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,113	01/09/2002	Ronald L. Ream	112703-201	9176

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EXAMINER	
HOWARD, SHARON LEE	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,113	REAM ET AL.	
	Examiner	Art Unit	
	Sharon L. Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Receipt of the Amendment and the Remarks filed on 11/14/05 have been acknowledged. Applicant please note that the rejection over claims 8-20 claiming the same invention as Claims 8-15,36-48 of U.S. Application No. 10/206,492 has been considered withdrawn. Claims 8-20 remain pending in this application.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Monte (U.S. Patent No. 5,578,336).

Monte teaches a chewing gum composition consisting of a gum center which comprises layers of coatings, in which one layer is coated with a vitamin (vitamin defines the medicament as claimed by applicant) (see the abstract and cols.3 and 4). Monte discloses sugarless sweetners, as well as xylitol and maltitol which reads on claim 11. Xylitol and maltitol defines a taste masking agent (see cols.2 and 3). At col.3,

lines 18-23 and col.12, example 29, Monte discloses the coating composition is applied to the gum center in a coating layers.

Monte does not teach the particular amounts of the coating nor the amounts of the taste masking agent.

However, absent a showing in the criticality of the particular amounts, there are no unexpected results, the Monte reference does teach a gum center which is coated with a medicament. Through routine experimentation, the particular amounts can be readily determined by one skilled in the pharmaceutical art.

The expected result would be to provide drug delivery to a gum center product with comprises a medicament in a coating layer.

No claims allowed.

Response to Arguments

Applicant's arguments filed 11/10/05 have been fully considered but they are not persuasive. Applicant argues that all of the claimed elements are not taught or suggested by *Monte.* For example, in contrast to the present claims, *Monte* fails to disclose or suggest a coating comprising at least 50% by weight of the product. Instead, *Monte* only discloses that its product has coating layers. See, *Monte,* column 2, lines 62-67.

Applicants respectfully disagree with the Patent Office's assertions that the claimed coating limitations are not entitled to any patentable weight. The claimed

coating levels are not conventionally used in the confectionery industry, and thus, these levels would not be obvious. *Monte* fails to even suggest a product having at least 50% by weight of a coating as required by Claims 8 and 16. In fact, *Monte* fails to suggest the problems that Applicants' invention seeks to overcome. Regardless, Applicants have demonstrated the importance of the claimed coating levels. Conventional consumable centers do not contain a significant amount of coating by weight of the product. Nowhere does *Monte* recognize or successfully employ the benefits of medicament absorption through the oral mucosa. Applicants respectfully submit that Claims 8 and 16 in this Application which currently requires "a consumable center" are patentably distinct from Claim 8 in Application No. 10/206,492 which now requires "a tableted center comprising at least one compressible saccharide or sugar alcohol." Similarly, Claims 8 and 16 are distinct from independent Claim 44 of the 10/206,492 application which currently requires "a center that is defined by at least one excipient" because consumable centers need not contain excipients. Also, in view of the distinctions between the independent claims of the two applications, Applicants respectfully submit that Claims 8-20 do not claim the same invention as Claims 8-15 and 36-48 of U.S. Patent Application No. 10/206,492. Accordingly, Applicants respectfully request that the double patenting rejection of Claims 8-20 under 35 U.S.C. 101 be withdrawn.

In response to applicant's arguments above, the *Monte* reference teaches a gum center comprising coating layers, in which one layer is coated with a vitamin (a vitamin can be defined as a medicament) (see the abstract and cols.3 and 4). Although the

reference does not teach a tableted center per se, the reference does suggest the teachings of a tableted center comprising a gum center which consists of a layer coated with a vitamin. Also, in particular, Example 1 at column 6 shows the presence of sugar and sugar is a saccharide. Since the coating is a medicament, there is no criticality of 50%. The amount of the medicament depends on the conditions of the disease, including other parameters such as the weight of the patient. Also, Applicants' argument with respect to base claim 8 in both applications are patentably distinct and that Claims 8-20 do not claim the same invention as Claims 8-15,36-48 of U.S. Patent Application No. 10/206,492 have been fully considered and are persuasive.

The rejection is maintained for reasons set forth above and is deemed obvious. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Howard
3/3/06

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